Application No. 08/499,423

II. APPLICANTS' INVENTION

The present invention relates to a porous polytetrafluoroethylene tube that circumferentially distends from an initial circumference upon the application of a circumferentially distending force such as applied by an internal pressure, and which exhibits minimal recoil following the removal of the circumferentially distending force. The porous polytetrafluoroethylene tube preferably has a second circumference larger than the initial circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The porous polytetrafluoroethylene tube itself provides the circumferential distensibility up to the limit, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The tube is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilitation of the blood vessel into which it is fitted.

III. REJECTION OF CLAIMS 2-23, 34, 35, 70-73, 78-81, 89 AND 90 UNDER 35 USC 112, SECOND PARAGRAPH AS BEING INDEFINITE.

Claims 2, 34, 70, 78, 89 and 90 are canceled herein. Claims 3, 5, 35, 71, 72, 79 and 80 are amended to correct dependency resulting from the cancellation of the claims from which they previously depended. Claim 6 is amended to revise redundant language. Applicants appreciatively acknowledge the Examiner's pointing out the redundant claim language resulting from the prior amendment of independent claims 1, 33 and 42. The amendment overcomes the 35 USC 112 second paragraph rejection.

IV. REJECTION OF CLAIMS 1-5, 24-26, 32-35 AND 86-91 UNDER 35 USC 102(b) AS BEING ANTICIPATED BY WEADOCK et al., US 5,665,114 AND DELLA CORNA et al., US 4,955,899.

The Examiner rejected these claims over Weadock et al. and Della Corna et al., stating that both references comprise porous PTFE which is known to exhibit minimal compliance (or expansion of circumference with pressure increase) and that porous PTFE has an inherent elastic

limit which would prevent circumference change up to the elastic limit (or possible burst pressure of the graft).

Weadock et al. teach an implantable tubular prosthesis in the form of an ePTFE tube wherein the pores of the tube are filled with a fluid which solidifies and is cross-linked to form a solid precipitate material of natural origin. Della Corna et al. teach an ePTFE vascular graft that is made to be longitudinally compliant by providing an ePTFE tube with an exterior coating of an elastomer.

Both of these ePTFE-based implantable devices have the same fundamental behavior with regard to pressure vs. diameter as do the prior art ePTFE tubes described in the background of the present application. Please see page 2, line 15 to page 3, line 2, particularly the paragraph beginning at page 2, line 29 describing the prior use of GORE-TEX® vascular Grafts and IMPRA® Grafts (Della Corna et al. being assigned to Impra). Briefly, the GORE-TEX® Vascular Grafts are longitudinally extruded and expanded (by longitudinal stretching) ePTFE tubes that are provided with a helical wrap of ePTFE film that results in a graft with resistance to dilitation; the graft will maintain substantially the same diameter until the pressure reaches a level that will cause the onset of rupture. When this pressure is achieved, the graft will very quickly rupture. The IMPRA® Graft is made in the same fashion except that it is not provided with the helical film wrap. The diameter of such a tube can be expected to increase continually with steadily increasing pressure until the onset of rupture, at which point further increasing pressure will result in abrupt rupture in a manner similar to the GORE-TEX® Vascular Graft.

The present graft differs from all of these prior art ePTFE tubes (including Weadock et al. and Della Corna et al. because it is manufactured in an entirely different and new manner; please see the flow chart of Figure 4. As a result, the graft of the present invention is able to be provided at a small diameter for catheter insertion into the vasculature (e.g., 1 mm, per Example 6, page 20), and then be increased in diameter (up to a pre-determined diameter, e.g., 8-9mm, again per Example 6) by a distending force such as supplied by a catheter balloon or even blood pressure, depending on the details of manufacture. Once this pre-determined diameter ("second circumference") is achieved, the inventive graft will resist further diametrical increase until pressures resulting in rupture are achieved. This behavior is entirely different from the behavior of the tubes of the cited references. They give absolutely no suggestion as to how an ePTFE tube might be made to allow a relatively low-pressure increase in diameter up to a limit (the "second circumference") might be provided. They simply do not provide the stable "second circumference" in any fashion. Rather, once the diameter of the prior art tubes is made to increase as a result of

the application of increasing pressure, it will steadily increase until failure. The behavior of the inventive tube is entirely novel and non-obvious in light of the cited references (because the process taught by Figure 4 of the instant application contains steps not suggested by the prior ePTFE art).

Della Corna et al. acknowledge that "PTFE material is not very elastic..." (col. 1, line51), as well as the "inability of PTFE vascular grafts to exhibit any longitudinal or *radial* compliance" (col. 2, lines 30-31, italics added). They specifically and repeatedly address longitudinal compliance but make absolutely no suggestion as to how any radial variability might be provided in an ePTFE tube. Weadock et al. rely on conventional ePTFE tubes to which they add a therapeutic naturally-occurring substance into the void space of the tube. They provide no teachings whatsoever as to the manufacturing of the ePTFE tube itself.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,

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Application No. 08/499,423

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Cancel claims 2, 34, 70, 78, 89 and 90.

Claim 3 has been amended as follows:

3. The tube of claim ~~2~~1 having a wall thickness less than or equal to about 0.25 mm.

Claim 5 has been amended as follows:

5. The tube of claim ~~2~~1 wherein said porous polytetrafluoroethylene has a microstructure of nodes interconnected by fibrils

Claim 6 has been amended as follows:

6. The tube of claim 5 ~~in which said tube comprises a porous polytetrafluoroethylene tube,~~ wherein said tube is ~~being~~ covered by one or more helical layers of porous polytetrafluoroethylene material.

Claim 35 has been amended as follows:

35. The article of claim 3~~4~~ wherein said tube is adapted for use as a vascular graft.

Claim 71 has been amended as follows:

71. A tube according to claim 4~~3~~70 wherein the tube has a wall thickness less than about 0.25 mm.

Claim 72 has been amended as follows:

72. A tube according to claim 4~~3~~70 wherein the circumference of the tube increases in response to the application of internal pressure up to a second circumference, thereafter the circumference remaining substantially unchanged with increasing internal pressure.

Application No. 08/499,423

Claim 79 has been amended as follows:

79. A tube according to claim 4478 wherein the vascular graft has a wall thickness less than about 0.25 mm.

Claim 80 has been amended as follows:

80. A tube according to claim 4478 wherein the circumference of said vascular graft increases in response to the application of internal pressure up to a second circumference, thereafter the circumference remaining substantially unchanged with increasing internal pressure.